

**Remarks**

Claims 1-33 were pending in the above-identified application. Claims 3, 4, 16, 17, 23, 26-29, 31, and 32 have been amended and claims 1, 2, 7-8, 12-15, 20-21, 25, 30, and 33 have been cancelled. No new claims have been added. Claims 3-6, 9-11, 16-19, 22-24, 26-29, and 31-32 are therefore now pending and under examination. Applicants respectfully request reconsideration and allowance of the claims in view of the amendments and the remarks provided herein.

**Claim Rejections under 35 U.S.C. §112**

Claims 1-33 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. More specifically, the rejection indicated that the specification does not enable one skilled in the art to make and use the invention commensurate in scope with claim 2. In particular, it was noted that there is no universal core structure for phthalocyanine molecules with physical and chemical properties indicative of the class of compounds. Applicants respectfully traverse the rejection, but have nonetheless cancelled claims 1 and 2 and corresponding method and salt claims of similar scope. Applicants respectfully assert that the amended claims recite a formula for phthalocyanine compounds that are fully enabled by the specification.

Claims 1-33 were also rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. More specifically, it was asserted that the claims contained subject matter not described in the specification to support Applicant's possession of the claimed invention. It was noted that claims 2-33 were rejected on this basis only for dependency on a rejected base claim. Applicants respectfully traverse the rejection, but have nonetheless cancelled claims 1 and 2 and corresponding method and salt claims of similar scope. Accordingly, Applicants respectfully request that the rejection of claims 1-33 under 35 U.S.C. §112, first paragraph, for lack of enablement and lack of possession be withdrawn.

**Claim Rejections under 35 U.S.C. §102**

Claims 1-33 were rejected under 35 U.S.C. §102(b) as being anticipated by several references. Applicants respectfully traverse the rejections, and address the individual references in more detail below.

Claims 1-33 were rejected as being anticipated by Taylor *et al.* (EP/0633024) and Love (EP/0720853). Due to the similarity of these references, they will be addressed together. Both Taylor *et al.* and Love describe only zinc phthalocyanines; *i.e.*, phthalocyanines in which the central metal ion is zinc. Applicants' amended claims, on the other hand, recite phthalocyanines in which the central metal ion Y is selected from Si, Al, Ga, Ge, or Sn. Because Taylor *et al.* and Love do not describe phthalocyanines including the central metal ions claimed, Applicants respectfully request that the rejections for anticipation of claims 1-33 by Taylor *et al.* and Love be withdrawn.

Claims 1-33 were also rejected as being anticipated by Cook *et al.* (WO 02/096913). Cook *et al.* only describe phthalocyanine compounds having a relatively simple axial region. More specifically, the axial region of the phthalocyanine compounds described by Cook *et al.* are Si(OX)<sub>2</sub>, in which X is defined as being H, CH<sub>3</sub>, or CH<sub>2</sub>CH<sub>3</sub>. See, for example, the compounds described on pages 14-16 of Cook *et al.* Applicants' claims, on the other hand, recite a more complex axial region (an alkylamine) described by the formula (G)<sub>a</sub>Y[(OSi(CH<sub>3</sub>)<sub>2</sub>(CH<sub>2</sub>)<sub>b</sub>N<sub>c</sub>(R')<sub>d</sub>(R'')<sub>e</sub>)<sub>f</sub>X<sub>g</sub>]<sub>p</sub>. The axial region described by this formula does not encompass the simple axial regions described by Cook *et al.* Because Applicants' claims do not encompass the phthalocyanine compounds described by Cook *et al.*, Applicants respectfully request that the rejection of claims 1-33 as being anticipated by Cook *et al.* be withdrawn.

Claims 1-33 were also rejected as being anticipated by Kenney *et al.* (WO 92/01753; referred to herein as Kenney '753. Kenney '753 is directed to developing phthalocyanines having superior photosensitizing ability (p. 8, line 32), describes the preparation of several phthalocyanine compounds, and recites several possible axial regions, one of which provides the compound Pc4 (for which the axial region is HOSiOSi(CH<sub>3</sub>)<sub>2</sub>(CH<sub>2</sub>)<sub>3</sub>N(CH<sub>3</sub>)<sub>2</sub>). However, Kenney '753 does not describe preparation of any of the claimed salts, or pharmaceutical

compositions for topical administration, as recited in claims 3 and 16. Kenney '753 does not provide a description of any pharmaceutical compositions, and administers the phthalocyanine compounds tested using dimethylformamide (DMF). Applicants, on the other hand, claim new pharmaceutically acceptable salt forms (claims 27-32), pharmaceutical compositions for topical administration (claims 3-11), and treatment including the step of topically administering a phthalocyanine pharmaceutical composition (claims 16-24). These claims are supported in the specification by an extensive listing of pharmaceutically acceptable salts (page 11) and a variety of topical formulations (page 12, line 30 to page 14, line 5), as well as test data regarding the uptake of salt forms and penetration of salts applied in topical formulations (pages 47-49). Because Applicants claims recite salts and topical pharmaceutical compositions not described by Kenney '753, Applicants respectfully request that the rejection of claims 1-33 as being anticipated by Kerrey '753 be withdrawn.

Claims 1-33 were also rejected as being anticipated by Kenney *et al.* (WO 95/06688; referred to herein as Kenney '688). As noted on page 10 at the end of the background section, Kenney '688 is directed to the preparation and analysis of additional new aluminum and silicon phthalocyanines beyond those previously developed by Kenney *et al.* However, Kenney '688 retains the focus of Kenney '753 on compound development and activity testing, rather than the development of new salt forms or pharmaceutical compositions for topical administration. Kenney '688 continues to describe administration of the phthalocyanines using DMF, but adds the use of corn oil. Nonetheless, Kenney '688 does not anticipate the topical pharmaceutical formulations and salt forms recited in the present claims, as described in greater detail above. Accordingly, Applicants respectfully request that the rejection of claims 1-33 as being anticipated by Kenney '688 be withdrawn.

#### **Claim Rejections under 35 U.S.C. §103**

Claims 1-33 were rejected under 35 U.S.C. §103(a) as being obvious in view of the same references cited for anticipation, namely Kenney '753, Kenney '688, Cook *et al.*, Taylor *et al.*,

and Love. More specifically, for each reference it has been asserted that the reference teaches a genus of phthalocyanine compounds for the treatment of epithelial cancer, and that it would have been obvious to one skilled in the art to select the claimed species from the genus described by the reference. Applicants respectfully traverse the rejection.

As noted above, Cook *et al.*, Taylor *et al.*, and Love do not describe compounds that fall within the scope of Applicants' amended claims. As a result, the assertion that the claims are *prima facie* obvious as a result of claiming species falling within a prior art genus is moot, because the claims, as amended, do not fall within the genus described by Cook *et al.*, Taylor *et al.*, and Love. Accordingly, Applicants respectfully request that the rejection of claims 1-33 as obvious over any one of Cook *et al.*, Taylor *et al.*, and Love be withdrawn.

Claims 1-33 were also rejected as being obvious over Kenney '753 or Kenney '688 on the same basis. However, Kenney '753 and Kenney '688 do not teach or suggest the preparation of the claimed pharmaceutical salts or the preparation of topical pharmaceutical formulations claimed by Applicants. Furthermore, Applicants have demonstrated that the recited salts and formulations exhibit improved uptake and delivery of the active phthalocyanine compounds, respectively, as shown in the Examples. Because an argument for the obviousness of the salts and/or topical pharmaceutical formulations has not been made by the Examiner, and because of the unexpected results obtained with these salts and/or topical pharmaceutical formulations, Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness, and furthermore even if a *prima facie* case had been established, Applicants respectfully submit that it would be overcome by Applicants' unexpected results. Accordingly, Applicants respectfully request that the rejection of claims 1-33 for being obvious over Kenney '753 or Kenney '688 be withdrawn.

RESPONSE TO OFFICE ACTION  
Appln. No. 10/599,433  
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In view of the above remarks, Applicants submit that claims 3-6, 9-11, 16-19, 22-24, 26-29, and 31-32 are in condition for allowance, and respectfully requests same. The Examiner is asked to contact the undersigned at the phone number listed below if there are any questions regarding the remarks provided herein.

Respectfully submitted,

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